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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 22, 1997

Our Reference: 29-52383

Fernando L. Fredrico, President
Lusamerica Foods, Inc.
1325 East Julian Street
San Jose, CA 95116

WARNING LETTER

Dear Mr. Fredrico:

On May 13, 1997, Investigators Darla R. Bracy and Mark I. Nakano conducted an inspection of your seafood processing plant in San Jose. During the inspection the investigators documented several violations of the Federal Food, Drug, and Cosmetic Act (the Act). Specifically, food products were prepared, packed, or held under insanitary conditions as follows:

Raw squid in a perforated plastic basket was observed to be stored directly over an uncovered plastic tray containing cooked imitation crab meat.

Cooked and raw seafood stored in uncovered blue styrofoam trays were observed stacked on top of one another in a manner whereby raw products could contaminate ready to eat products.

Raw uncovered sand dabs in a perforated plastic basket were observed on the floor in the processing room.

Raw unrefrigerated seafoods with no ice were stored in filleting and packing rooms from midnight until 4:30am. Products included salmon steaks, halibut steaks, mahi mahi, mussels, clams, and oysters. Temperatures taken of the various products ranged from 40° F - 45° F.

The cooler drip pan for excess condensate was observed overflowing and splashing onto the cooler floor near stored boxes of seafood.

Poor employee practices were observed, which included an employee putting plastic product bags into his mouth, and employees packing ready to eat and raw seafood wearing dangling earrings.

Poor housekeeping practices were observed in the employee restrooms including, standing water in the men's restroom, and a clogged toilet in the women's restroom.

Under Section 402(a)(4) of the Act, foods held under such conditions are adulterated, in that they are prepared, packed, or held under insanitary conditions whereby they may become contaminated with filth, or whereby they may be rendered injurious to health.

In conjunction with the inspection, FDA collected and analyzed a sample (DI 97-732-228) of albacore tuna loins and found it to be decomposed. This lot of tuna is deemed adulterated within the meaning of Section 402(a)(3) the Act in that the tuna consists in whole or in part of a decomposed substance.

We are particularly concerned that you have been notified during previous FDA inspections, on July 14, 1995, and December 8, 1995, of similar GMP violations and continue to operate in such a manner.

At the conclusion of the inspection, the insanitary conditions and poor employee and housekeeping practices were listed on Form FDA 483 (Inspectional Observations) and were discussed in detail with Mr. Anthony J. Silva, Plant Manager. A copy of this is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. You must take prompt action to correct these violations on a permanent basis. Failure to promptly implement adequate corrections may result in regulatory action without further notice.

Please advise this office in writing, within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct GMP violations and to prevent their recurrence . Please direct your response to Erlinda Figueroa, Compliance Officer.

Sincerely,

Patricia C. Ziobro
District Director

Attachment: Form FDA 483